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**STATE OF DELAWARE**  
**BOARD OF PHARMACY**

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<b>PUBLIC MEETING NOTICE:</b>	<b>BOARD OF PHARMACY</b>
<b>DATE AND TIME:</b>	<b>Wednesday, June 17, 2015 9:30 am</b>
<b>PLACE:</b>	Conference Room A, 2 <sup>nd</sup> Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
<b>APPROVED:</b>	August 19, 2015

**MEMBERS PRESENT**

Kenneth Sellers, Public Member, President  
Susan Esposito, R.Ph., Professional Member, Vice President  
Joli Martini, R.Ph., Professional Member  
Kimberly Robbins, R.Ph., Professional Member arrived at 9:40 am  
Tejal Patel, PharmD, Professional Member  
Hooshang Shanehsaz, R.Ph., Professional Member  
Jay Galloway, Public Member

**MEMBERS ABSENT**

Bonnie Wallner, R.Ph., Professional Member  
Julia Wheatley, Public Member

**DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT**

David Dryden, Executive Secretary  
Eileen Kelly, Deputy Attorney General  
Christine Mast, Administrative Specialist III  
Samantha Nettesheim, Pharmacist Administrator  
Michelle McCreary, Pharmacist Compliance Officer

**ALSO PRESENT**

Suzanne Raab-Long  
Tom McLean  
Tom Rasnic  
Ralph Napolitano  
Percy Dhamodiwala  
Karen Ford  
Abhishu De  
Marianna Koerner  
Judee Olimpo  
Bill Harbester  
David Leach  
Kapil Patel  
Tiffany Storey  
Elizabeth Ryan  
Jay C Patel

### **CALL TO ORDER**

Mr. Sellers called the meeting to order at 9:32 a.m.

### **REVIEW OF MINUTES**

A motion was made by Ms. Martini and seconded by Ms. Esposito, to approve the meeting minutes for May 20, 2015. The motion unanimously carried.

### **PRESIDENT'S REPORT**

Mr. Sellers reported that he is adding Mr. Hooshang Shanehsaz to the legislative committee. The committee will now have 5 members.

### **UNFINISHED BUSINESS**

#### **Complaint Status**

- 13-09-11 – Assigned to Hearing Officer
- 13-12-11 – Assigned to Hearing Officer
- 13-19-11 – Forwarded to Office of Attorney General
- 13-01-13 – Forwarded to Office of Attorney General
- 13-04-13 – Forwarded to Office of Attorney General
- 13-05-13 – Forwarded to Office of Attorney General
- 13-06-13 – Forwarded to Office of Attorney General
- 13-20-13 – Forwarded to Office of Attorney General
- 13-26-13 – Assigned to Hearing Officer
- 13-01-14 – Forwarded to Office of Attorney General
- 13-03-14 – Assigned
- 13-04-14 – Assigned
- 13-05-14 – Assigned
- 13-06-14 – Forwarded to Office of Attorney General
- 13-07-14 – Forwarded to Office of Attorney General
- 13-08-14 – Assigned
- 13-09-14 – Forwarded to Office of Attorney General
- 13-10-14 – Forwarded to Office of Attorney General
- 13-11-14 – Forwarded to Office of Attorney General
- 13-12-14 – Forwarded to Office of Attorney General
- 13-13-14 – Assigned
- 13-14-14 – Forwarded to Office of Attorney General
- 13-15-14 – Assigned
- 13-16-14 – Assigned
- 13-17-14 – Assigned

A motion to move forward in the agenda was made by Ms. Martini seconded by Ms. Robbins. The motion carried unanimously.

#### **Proposal to Deny Hearing**

Par Sterile Products, a motion was made to approve the application by Mr. Shanehsaz seconded by Ms. Martini. The motion unanimously carried.

PharMEDium Services, a motion was made to approve the application by Ms. Martini seconded by Mr. Galloway.

#### **Re-Review of Tabled Applications**

Cystic Fibrosis Services, a motion was made to propose to deny the application by Ms. Martini seconded by Mr. Shanehsaz.

#### **Final Order Review**

Leonard Bronstein, the order was signed by Ms. Martini.

### Statutory and Regulatory Discussion

- Practitioner/Pharmacy Ownership. Ms. Kelly will prepare requested changes in bill format for review for the January 2016 Legislative session.
- Provision for Disciplinary Action. Ms. Tejal Patel presented information on the Pharmacist Assessment Remediation Evaluation (P.A.R.E.) for the board to review. This can be used as an assessment tool for pharmacist returning from Inactive status and/or returning to active status after a disciplinary action. The board determined that this may be an option to be utilized going forward on a case by case basis.
- Pharmacy Technician Regulation. Ms. Kelly will prepare requested changes in bill format for review for the January 2016 Legislative session.
- Clarification of §2512(e)(f), Inactive Status, Ms. Kelly will prepare requested changes in bill format for review for the January 2016 Legislative session.
- Review of Crimes Listing - The Legislative Committee meeting to meet on June 17, 2015 after the regular board meeting.

### Application Requirements regarding Inspection

Mr. Shanehsaz suggested possible utilization of the National Boards of Pharmacy, Verified Pharmacy Program for out of state applications. Utilization of this program would provide assurance that the pharmacy had been properly inspected. Some states do not require licensure or inspections. The expense of this requirement would be assumed by the licensee. Receiving this inspection report as verification of inspection would expedite the application approval process. Ms. Mast will contact NABP for those rates and report back to the board the next scheduled meeting.

### **NEW BUSINESS**

Mr. Sellers read into the record the following ratifications:

#### Pharmacist and Intern Licensure Approval Ratifications

**Pharmacist:** A1-0004748 Marianne Bious  
A1-0004749 Bonita Dunbar Buesmaill  
A1-0004750 Ha B. Hoang  
A1-0004751 Lorraine Lombos Asa  
A1-0004752 Tara D. Kompare  
A1-0004753 Kevin Steger

A motion was made by Ms. Robbins and seconded by Ms. Martini to approve the ratification of the Pharmacist applications. The motion unanimously carried.

**Pharmacist Intern:** A7-0002393 David A. McGain  
A7-0002394 Jeffrey Allen Perrone  
A7-0002395 Carolyn Dyan Cooper  
A7-0002396 Hetalben B. Patel  
A7-0002397 Coleen A. McCarren

A motion was made by Ms. Robbins and seconded by Ms. Martini to approve the ratification of the Pharmacist Intern applications. The motion unanimously carried.

#### Non-Resident Pharmacy Licensure Approval Ratifications

A9-0001638 Gardens Pharmacy LLC  
A9-0001639 Econo Pharmacy Inc.  
A9-0001640 Raindrop Pharmacy  
A9-0001641 Neighborhood Pharmacy  
A9-0001642 One Source Rx, LLC  
A9-0001643 Mesa Pharmacy Inc.  
A9-0001644 Heartland Veterinary Pharmacy LLC  
A9-0001645 Reeves-Sain Drug Store, Inc. DBA EntrustRX

A9-0001646 BioRx  
A9-0001647 Lantana Pharmacy  
A9-0001648 River Medical Pharmacy Inc  
A9-0001649 EDPHARMALLC  
A9-0001650 Greywell Pharmacy  
A9-0001651 Dunn Meadow LLC  
A9-0001652 Shields Drugs, Inc.

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A4-0001471 ProVen Pharmaceutical LLC  
A4-0002201 Exel Inc.  
A4-0002202 HealthSource Distributors, LLC  
A4-0002203 ProPharma Distribution, LLC  
A4-0002205 Exel Inc.  
A4-0002206 PureLife, LLC  
A4-0002207 The Procter & Gamble Distributing LLC  
A4-0002208 Carlsbad Technology, Inc.

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Medical Gas Dispensers

A2-0000129 Advanced Home Care, Inc.  
A2-0000130 Nationwide Medical, Inc.

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Medical Gas Dispensers applications. The motion unanimously carried.

Retail Pharmacy Licensure Approval Ratification

A3-0000853 Rite Aid #11192  
A3-0000985 Sussex Pharmacy  
A3-0000986 Accredo Health Group, Inc.

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Retail Pharmacy applications. The motion unanimously carried.

Retail Pharmacy Temporary Licensure Approval Ratification

None

Outsourcing Facility

None

Pharmacist-In-Charge Interviews

Ms. Robbins conducted PIC interviews with:  
Percy Dhamodiwala, Sussex Pharmacy Millsboro, De.  
Thomas McLean, PRMC Home Scripts, Millsboro, DE

Consultant Pharmacist Interviews

None

### Review of Applications by DAG

American Pharmaceutical Ingredients, LLC a motion to approve was made by Ms. Martini seconded by Mr. Galloway. Mr. Shanehsaz was absent. The motion carried.

Sun Pharmaceutical Industries, Inc. a motion to propose to deny was made by Mr. Shanehsaz seconded by Ms. Esposito. The motion carried unanimously.

Avella of Deer Valley a motion to table for more information was made by Ms. Martini seconded by Ms. Patel. The motion carried unanimously.

APL Logistics Warehouse Management Services, CA a motion to propose to deny was made by Ms. Esposito seconded by Mr. Shanehsaz. The motion carried unanimously.

APL Logistics Warehouse Management Services, GA a motion to propose to deny was made by Ms. Esposito seconded by Mr. Shanehsaz. The motion carried unanimously.

APL Logistics Warehouse Management Services, WI a motion to propose to deny was made by Ms. Esposito seconded by Mr. Shanehsaz. The motion carried unanimously.

APL Logistics Warehouse Management Services, PA a motion to propose to deny was made by Ms. Esposito seconded by Mr. Shanehsaz. The motion carried unanimously.

APL Logistics Warehouse Management Services, TX a motion to table was made by Ms. Martini seconded by Ms. Esposito. The motion carried unanimously.

Boehringer Ingelheim Vetmedica, Inc. a motion to approve was made by Ms. Robbins seconded by Ms. Esposito. The motion carried unanimously.

Crown Laboratories, Inc. TN\* a motion to approve was made by Ms. Robbins seconded by Mr. Galloway. The motion carried unanimously.

Adeola Olufunmilayo Edema a motion to approve was made by Mr. Galloway seconded by Ms. Robbins. The motion carried unanimously.

### Rite Aid Buccal Swab Presentation

Ms. Karen Ford, Clinical Services Manager Rite Aid spoke regarding buccal swab for pharmacogenetics. Ms. Ford stated that Harmonics Labs provides the screening test kits. There are 3 screens available; Plavix, Simvastatin, ADHD. The pharmacist offers the test kit to the patient and explains the testing benefit to the customer. The patient performs the swab. The test kit is sent to Harmonics Labs for evaluation and the results are returned to: the patient, the pharmacist and the patient's practitioner. The results are discussed with the patient by the practitioner and/or the pharmacist. There is out of pocket expense associated with the test kit. There is no prescription required. Mr. Dryden and the board discussed the statute and agreed that this would not be out of the scope of practice since the patient does the swab and not the pharmacist. The patient's medications would only be changed after consulting with the practitioner.

### COMMITTEE REPORTS

**Legislative** – Joli Martini, Jay Galloway, Kim Robbins, Tejal Patel, Hooshang Shanehsaz and David Dryden

No Report, a meeting is scheduled immediately following the board meeting.

**Continuing Education** – Joli Martini, Bonnie Wallner, Tejal Patel and David Dryden:

No Report

**Consumer Affairs** – Ken Sellers, Jay Galloway and Julia Wheatley

No Report

**Professional Liaisons** – Kim Robbins and Tejal Patel:

Ms. Robbins reported that Delaware Pharmacist Society (DPS) had their final meeting of the year. Mr. Harbester reported he has fulfilled his role as president for DPS and that Liz Ryan has been elected as the new incoming president for the next year. Mr. Shanehsaz reported that DPS is starting a pilot program in Delaware for medication disposal. Five independent pharmacies will be included in the pilot. Mr. Harbester also noted that on June 28<sup>th</sup> there will be a 5k run /walk in memory of Don Holst to raise scholarship funds in his name.

**Controlled Substance Liaisons** – Kenneth Sellers, Tejal Patel, Jay Galloway and David Dryden:

Mr. Dryden reported that the committee is currently working on Safe Opioid Prescribing regulations changes. There will be a hearing held July 29, 2015.

**Patient Safety Committee** – Michelle McCreary (Chair), Kenneth Sellers, Tejal Patel, Kimberly Robbins, Susan Esposito, Joli Martini, Hooshang Shanehsaz, Jay Patel

Ms. McCreary presented the board with proposed regulations changes regarding disciplinary action taken against the pharmacist in charge for technician support. The committee is proposing to change regulation 3.8 responsibility from the pharmacist in charge to the facility licensee. Secondly the committee reviewed the training of the technician to assure that a fully trained pharmacy technician is available and on the schedule when the pharmacist calls for assistance. The committee expressed the desire to have this become part of the routine inspection to ensure compliance. A motion was made by Mr. Shanehsaz and seconded by Ms. Esposito to approve the proposed regulation's changes as presented. The motion carried unanimously.

#### **COMMITTEE UPDATES REGARDING PROPOSED REGULATIONS**

**USP 795 & 797 Committee** – Tejal Patel, Brenda Pavlic, Hooshang Shanehsaz, Calvin Freedman and David Dryden:

Ms. Kelly reported that the proposed changes were to be published in the register of regulations on July 1, 2015 for hearing scheduled on August 19, 2015.

**Collaborative Care Committee** – Bonnie Wallner, Cheri Briggs, Cheryl Heiks, Drew Wilson, Deborah Hamilton, Joli Martini, Julie Miro-Wenger, Mark Thompson, Mike Perza, Nick Biasotto, Pooja Dogra, Tejal Patel, Terri Corbo, William Harbester, David Dryden:

No Report

#### **BOARD CORRESPONDENCE**

None

#### **EXECUTIVE SECRETARY, INSPECTION & PMP REPORT - David Dryden, Michelle McCreary, Samantha Nettesheim**

Mr. Dryden reported that he and Tejal Patel attended the NABP National meeting.

Mr. Dryden also reported that the .pharmacy domain for Delaware is nearing completion.

Mr. Dryden stated that Ms. Mast would be attending the NABP training in July. This training provides insight into the many resources NABP provides to licensing boards.

Ms. McCreary reported that 24 routine inspections, 1 FDA, 1 New Pharmacy, 1 DEA, 1 Research Lab and 1 Change of Ownership inspection(s) have been completed for the month. She also assisted with 2 investigations. Ms. McCreary queried the board to see if they continue to support the dual inspection process with the FDA inspector that is currently in place. The board choose not to make any changes with that protocol.

Ms. Nettesheim reported that the ongoing upgrade discussions are still on going. The vendor has moved this upgrade completion to December 2015. Ms. Nettesheim reported that she had a meeting with her counterpart in New Jersey. There discussions included comparisons of the PMP, data sharing, ways to improve current reporting as well as systems pros and cons.

Ms. Nettesheim reported that University of Delaware has started their download of data to begin the geo-mapping project.

#### **NEWSLETTER UPDATES**

No Report

#### **OTHER BUSINESS BEFORE THE BOARD**

None

#### **PUBLIC COMMENT**

Mr. Harbester commended the patient safety committee for proposed regulatory changes they have reviewed and will be offering for hearing.

#### **NEXT SCHEDULED MEETING**

The next meeting is scheduled for August 19, 2015 at 9:30 Am., Conference Room A 2<sup>nd</sup> floor.

**ADJOURNMENT**

There being no other business before the Board a motion to adjourn the meeting was made by Ms. Patel, seconded by Esposito at 12:13 am.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mast". The signature is written in a cursive, flowing style.

Christine Mast  
Administrative Specialist III  
Liaison, Board of Pharmacy